

AMENDMENTS TO THE CLAIMS

The following Listing of Claims will replace all prior versions, and listings, of claims in the application:

1. **(Currently amended)** A method ~~of classifying a tumor~~ comprising the steps of:
providing a tumor sample;
detecting expression or activity of a gene encoding the polypeptide of SEQ ID NO:1 in the sample; and
classifying the tumor as belonging to a tumor subclass based on the results of the detecting step.
2. **(Currently amended)** A method ~~of classifying a tumor~~ comprising the steps of:
providing a tumor sample;
detecting expression or activity of a gene encoding the polypeptide of SEQ ID NO:2 in the sample; and
classifying the tumor as belonging to a tumor subclass based on the results of the detecting step.
3. **(Currently amended)** A method ~~of classifying a tumor~~ comprising the steps of:
providing a tumor sample;
detecting expression or activity of a gene encoding the polypeptide of SEQ ID NO:3 in the sample; and
classifying the tumor as belonging to a tumor subclass based on the results of the detecting step.
4. **(Currently amended)** A method ~~of classifying a tumor~~ comprising the steps of:
providing a tumor sample;
detecting expression or activity of at least two genes selected from the group consisting of: a gene encoding the polypeptide of SEQ ID NO:1, SEQ ID NO:2, and SEQ ID NO:3 in the

sample; and

classifying the tumor as belonging to a tumor subclass based on the results of the detecting step.

5. **(Original)** The method of any of claims 1, 2, 3, or 4, wherein the detecting step comprises detecting the polypeptide or polypeptides.
6. **(Original)** The method of claim 5, wherein the polypeptide is detected by performing immunohistochemical analysis on the sample using an antibody that specifically binds to the polypeptide.
7. **(Original)** The method of claim 5, wherein the polypeptide is detected by performing an ELISA assay using an antibody that specifically binds to the polypeptide.
8. **(Original)** The method of claim 5, wherein the polypeptide is detected using an antibody array comprising an antibody that specifically binds to the polypeptide.
9. **(Currently amended)** The method of claim 5, wherein the polypeptide is detected by ~~detecting step comprises:~~ detecting modification of a substrate by the polypeptide.
10. **(Currently amended)** The method of any of claims 1, 2, 3, or 4, wherein, in the step of providing, the sample is isolated from a subject having a tumor, the method further comprising ~~classifying a tumor comprises:~~
stratifying the a subject having the tumor for a clinical trial based on the results of the ~~classifying step.~~
11. **(Original)** The method of claim 10, wherein the tumor is a breast tumor.
12. **(Original)** The method of any of claims 1, 2, 3, or 4, wherein the tumor is a breast tumor

and the tumor subclass is a basal tumor subclass.

13. **(Withdrawn)** The method of claim 1, further comprising:
providing diagnostic, prognostic, or predictive information based on the classifying step.
14. **(Withdrawn)** The method of claim 2, further comprising:
providing diagnostic, prognostic, or predictive information based on the classifying step.
15. **(Original)** The method of claim 3, further comprising:
providing diagnostic, prognostic, or predictive information based on the classifying step.
16. **(Original)** The method of claim 4, further comprising:
providing diagnostic, prognostic, or predictive information based on the classifying step.
17. **(Original)** The method of claim 5, further comprising:
providing diagnostic, prognostic, or predictive information based on the classifying step.
18. **(Original)** The method of claim 17, wherein the polypeptide is detected by performing immunohistochemical analysis on the sample using an antibody that specifically binds to the polypeptide.
19. **(Original)** The method of claim 17, wherein the polypeptide is detected by performing an ELISA assay using an antibody that specifically binds to the polypeptide.
20. **(Original)** The method of claim 17, wherein the polypeptide is detected using an antibody array comprising an antibody that specifically binds to the polypeptide.
21. **(Currently amended)** The method of claim 17, wherein the polypeptide is detected by ~~detecting step comprises:~~ detecting modification of a substrate by the polypeptide.

22. **(Original)** The method of any of claims 13, 14, 15, or 16, wherein the tumor is a breast tumor and the tumor subclass is a basal tumor subclass.
23. **(Withdrawn)** The method of claim 1, further comprising:
selecting a treatment based on the classifying step.
24. **(Withdrawn)** The method of claim 2, further comprising:
selecting a treatment based on the classifying step.
25. **(Original)** The method of claim 3, further comprising:
selecting a treatment based on the classifying step.
26. **(Original)** The method of claim 4, further comprising:
selecting a treatment based on the classifying step.
27. **(Original)** The method of claim 5, further comprising:
selecting a treatment based on the classifying step.
28. **(Original)** The method of claim 27, wherein the polypeptide is detected by performing immunohistochemical analysis on the sample using an antibody that specifically binds to the polypeptide.
29. **(Original)** The method of claim 27, wherein the polypeptide is detected by performing an ELISA assay using an antibody that specifically binds to the polypeptide.
30. **(Original)** The method of claim 27, wherein the polypeptide is detected using an antibody array comprising an antibody that specifically binds to the polypeptide.

31. **(Currently amended)** The method of claim 27, wherein the polypeptide is detected by detecting step comprises: detecting modification of a substrate by the polypeptide.
32. **(Original)** The method of any of claims 23, 24, 25, or 26, wherein the tumor is a breast tumor and the tumor subclass is a basal tumor subclass.
33. **(Currently amended)** A method ~~of testing a subject~~ comprising the steps of:
providing a sample isolated from a subject having a tumor;
detecting expression or activity of a gene encoding the polypeptide of SEQ ID NO:1 in the sample; and
providing diagnostic, prognostic, or predictive information about the subject based on the results of the detecting step.
34. **(Currently amended)** A method ~~of testing a subject~~ comprising the steps of:
providing a sample isolated from a subject having a tumor;
detecting expression or activity of a gene encoding the polypeptide of SEQ ID NO:2 in the sample; and
providing diagnostic, prognostic, or predictive information about the subject based on the results of the detecting step.
35. **(Currently amended)** A method ~~of testing a subject~~ comprising the steps of:
providing a sample isolated from a subject having a tumor;
detecting expression or activity of a gene encoding the polypeptide of SEQ ID NO:3 in the sample; and
providing diagnostic, prognostic, or predictive information about the subject based on the results of the detecting step.
36. **(Currently amended)** A method ~~of testing a subject~~ comprising the steps of:
providing a sample isolated from ~~a~~ the subject having a tumor;

detecting expression or activity of at least two genes selected from the group consisting of: a gene encoding the polypeptide of SEQ ID NO:1, SEQ ID NO:2, and SEQ ID NO:3 in the sample; and

providing diagnostic, prognostic, or predictive information about the subject based on the results of the detecting step.

37. **(Original)** The method of any of claims 33, 34, 35, or 36, wherein the detecting step comprises detecting the polypeptide or polypeptides.

38. **(Original)** The method of claim 37, wherein the polypeptide is detected by performing immunohistochemical analysis on the sample using an antibody that specifically binds to the polypeptide.

39. **(Original)** The method of claim 37, wherein the polypeptide is detected by performing an ELISA assay using an antibody that specifically binds to the polypeptide.

40. **(Original)** The method of claim 37, wherein the polypeptide is detected using an antibody array comprising an antibody that specifically binds to the polypeptide.

41. **(Currently amended)** The method of claim 37, wherein the polypeptide is detected by ~~detecting step comprises:~~ detecting modification of a substrate by the polypeptide.

42. **(Original)** The method of any of claims 33, 34, 35, or 36, wherein the sample is selected from the group consisting of:

a blood sample, a urine sample, a serum sample, an ascites sample, a saliva sample, a cell, and a portion of tissue.

43. **(Original)** The method of any of claims 33, 34, 35, or 36, wherein the sample is a tumor sample.

44. **(Original)** The method of claim 43, wherein the tumor sample is a breast tumor sample.
45. **(Currently amended)** A method ~~of testing a subject~~ comprising the steps of:
providing a sample isolated from a subject having a tumor;
detecting expression or activity of a gene encoding the polypeptide of SEQ ID NO:1 in
the sample; and
stratifying the subject for a clinical trial based on the results of the detecting step.
46. **(Currently amended)** A method ~~of testing a subject~~ comprising the steps of:
providing a sample isolated from a subject having a tumor;
detecting expression or activity of a gene encoding the polypeptide of SEQ ID NO:2 in
the sample; and
stratifying the subject for a clinical trial based on the results of the detecting step.
47. **(Currently amended)** A method ~~of testing a subject~~ comprising the steps of:
providing a sample isolated from a subject having a tumor;
detecting expression or activity of a gene encoding the polypeptide of SEQ ID NO:3 in
the sample; and
stratifying the subject for a clinical trial based on the results of the detecting step.
48. **(Currently amended)** A method ~~of testing a subject~~ comprising the steps of:
providing a sample isolated from ~~a the~~ subject having a tumor;
detecting expression or activity of at least two genes selected from the group consisting
of: a gene encoding the polypeptide of SEQ ID NO:1, SEQ ID NO:2, and SEQ ID NO:3 in the
sample; and
stratifying the subject for a clinical trial based on the results of the detecting step.
49. **(Original)** The method of any of claims 45, 46, 47, or 48, wherein the detecting step

comprises detecting the polypeptide or polypeptides.

50. **(Original)** The method of claim 49, wherein the polypeptide is detected by performing immunohistochemical analysis on the sample using an antibody that specifically binds to the polypeptide.

51. **(Original)** The method of claim 49, wherein the polypeptide is detected by performing an ELISA assay using an antibody that specifically binds to the polypeptide.

52. **(Original)** The method of claim 49, wherein the polypeptide is detected using an antibody array comprising an antibody that specifically binds to the polypeptide.

53. **(Currently amended)** The method of claim 49, wherein the polypeptide is detected by ~~detecting step comprises:~~ detecting modification of a substrate by the polypeptide.

54. **(Original)** The method of any of claims 45, 46, 47, or 48, wherein the sample is selected from the group consisting of:

a blood sample, a urine sample, a serum sample, an ascites sample, a saliva sample, a cell, and a portion of tissue.

55. **(Original)** The method of any of claims 45, 46, 47, or 48, wherein the sample is a tumor sample.

56. **(Original)** The method of claim 55, wherein the tumor sample is a breast tumor sample.

57. **(Currently amended)** A method of ~~testing a subject~~ comprising the steps of:
providing a sample isolated from a subject having a tumor;
detecting expression or activity of a gene encoding the polypeptide of SEQ ID NO:1 in the sample; and

selecting a treatment based on the results of the detecting step.

58. **(Currently amended)** A method ~~of testing a subject~~ comprising the steps of:
providing a sample isolated from a subject having a tumor;
detecting expression or activity of a gene encoding the polypeptide of SEQ ID NO:2 in
the sample; and
selecting a treatment based on the results of the detecting step.

59. **(Currently amended)** A method ~~of testing a subject~~ comprising the steps of:
providing a sample isolated from a subject having a tumor;
detecting expression or activity of a gene encoding the polypeptide of SEQ ID NO:3 in
the sample; and
selecting a treatment based on the results of the detecting step.

60. **(Currently amended)** A method ~~of testing a subject~~ comprising the steps of:
providing a sample isolated from ~~a the~~ subject having a tumor;
detecting expression or activity of at least two genes selected from the group consisting
of: a gene encoding the polypeptide of SEQ ID NO:1, SEQ ID NO:2, and SEQ ID NO:3 in the
sample; and
selecting a treatment based on the results of the detecting step.

61. **(Original)** The method of any of claims 57, 58, 59, or 60, wherein the detecting step
comprises detecting the polypeptide or polypeptides.

62. **(Original)** The method of claim 61, wherein the polypeptide is detected by performing
immunohistochemical analysis on the sample using an antibody that specifically binds to the
polypeptide.

63. **(Original)** The method of claim 61, wherein the polypeptide is detected by performing

an ELISA assay using an antibody that specifically binds to the polypeptide.

64. **(Original)** The method of claim 61, wherein the polypeptide is detected using an antibody array comprising an antibody that specifically binds to the polypeptide.

65. **(Currently amended)** The method of claim 61, wherein the polypeptide is detected by ~~detecting step comprises:~~ detecting modification of a substrate by the polypeptide.

66. **(Original)** The method of any of claims 57, 58, 59, or 60, wherein the sample is selected from the group consisting of:

a blood sample, a urine sample, a serum sample, an ascites sample, a saliva sample, a cell, and a portion of tissue.

67. **(Original)** The method of any of claims 57, 58, 59, or 60, wherein the sample is a tumor sample.

68. **(Original)** The method of claim 67, wherein the tumor sample is a breast tumor sample.

69. **(Withdrawn)** An antibody that specifically binds to an epitope found in a polypeptide whose amino acid sequence the amino acid sequence of SEQ ID NO:1, and wherein the antibody recognizes basal cells in normal mammary lactation glands.

70. **(Withdrawn)** The antibody of claim 69, wherein the antibody distinguishes basal cells from luminal cells in normal mammary lactation glands.

71. **(Withdrawn)** The antibody of claim 69, wherein the antibody is a monoclonal antibody.

72. **(Withdrawn)** The antibody of claim 69, wherein the antibody is a polyclonal antibody.

73. **(Withdrawn)** The antibody of claim 69, wherein the antibody recognizes an epitope found in a peptide having an amino acid sequence selected from the group consisting of SEQ ID NO:4, SEQ ID NO:5, and SEQ ID NO:6.
74. **(Withdrawn)** An antibody that specifically binds to an epitope found in a polypeptide whose amino acid sequence comprises the amino acid sequence of SEQ ID NO:2, and wherein the antibody recognizes basal cells in normal mammary lactation glands.
75. **(Withdrawn)** The antibody of claim 73, wherein the antibody distinguishes basal cells from luminal cells in normal mammary lactation glands.
76. **(Withdrawn)** The antibody of claim 73, wherein the antibody is a monoclonal antibody.
77. **(Withdrawn)** The antibody of claim 73, wherein the antibody is a polyclonal antibody.
78. **(Withdrawn)** The antibody of claim 73, wherein the antibody recognizes an epitope found in a peptide having an amino acid sequence selected from the group consisting of SEQ ID NO:7, SEQ ID NO:8, and SEQ ID NO:9.
79. **(Withdrawn)** An antibody that specifically binds to an epitope found in a polypeptide whose amino acid sequence comprises the amino acid sequence of SEQ ID NO:3, and wherein the antibody recognizes basal cells in normal mammary lactation glands.
80. **(Withdrawn)** The antibody of claim 79, wherein the antibody distinguishes basal cells from luminal cells in normal mammary lactation glands.
81. **(Withdrawn)** The antibody of claim 79, wherein the antibody is a monoclonal antibody.
82. **(Withdrawn)** The antibody of claim 79, wherein the antibody is a polyclonal antibody.

83. **(Withdrawn)** The antibody of claim 79, wherein the antibody recognizes an epitope found in a peptide having an amino acid sequence selected from the group consisting of SEQ ID NO:10, SEQ ID NO:11, and SEQ ID NO:12.

84. **(Withdrawn)** A kit for tumor diagnosis comprising:
one or more of the antibodies of any of claims 68 through 82;
instructions for use of the kit; and
a control slide comprising breast tissue samples for testing reagents in the kit.

85. **(Withdrawn)** A method of testing a compound or a combination of compounds for activity against tumors comprising steps of:
obtaining or providing tumor samples taken from subjects who have been treated with the compound or combination of compounds, wherein the tumors fall within a tumor subclass;
comparing the response rate of tumors that fall within the tumor subclass and have been treated with the compound with the overall response rate of tumors that have been treated with the compound or combination of compounds or with the response rate of tumors that do not fall within the subclass and have been treated with the compound or combination of compounds; and
identifying the compound or combination of compounds as having selective activity against tumors in the tumor subclass if the response rate of tumors in the subclass is greater than the overall response rate or the response rate of tumors that do not fall within the subclass.

86. **(Withdrawn)** The method of claim 85, wherein the tumors are breast tumors.

87. **(Withdrawn)** The method of claim 86, wherein the tumor subclass is a basal tumor subclass.

88. **(Withdrawn)** The method of claim 86, wherein the tumors are classified according to the method of any of claims 1, 2, 3, or 4.

89. **(Withdrawn)** The method of claim 86, wherein the tumor subclass is a basal tumor subclass and wherein a tumor is identified as belonging to the tumor subclass based on evidence of expression of one or more basal marker genes in the sample.

90. **(Withdrawn)** The method of claim 89, wherein evidence of expression comprises presence of a protein encoded by a basal marker gene, and wherein the evidence of expression is obtained using an antibody that binds to the protein.

91. **(Withdrawn)** The method of claim 90, wherein the basal marker gene encodes a polypeptide comprising the amino acid sequence of SEQ ID NO:1.

92. **(Withdrawn)** The method of claim 90, wherein the basal marker gene encodes a polypeptide comprising the amino acid sequence of SEQ ID NO:2.

93. **(Withdrawn)** The method of claim 90, wherein the basal marker gene encodes a polypeptide comprising the amino acid sequence of SEQ ID NO:3.

94. **(Withdrawn)** The method of claim 85, wherein the samples are present within a tissue array.

95. **(Withdrawn)** A method of testing a compound or a combination of compounds for activity against tumors comprising steps of:

treating subjects in need of treatment for tumors with the compound or combination of compounds;

comparing the response rate of tumors that fall within a tumor subclass with the overall response rate of tumors or with the response rate of tumors that do not fall within the subclass; and

identifying the compound or combination of compounds as having selective activity

against tumors in the tumor subclass if the response rate of tumors in the subclass is greater than the overall response rate or the response rate of tumors that do not fall within the subclass.

96. **(Withdrawn)** The method of claim 95, further comprising the steps of:
providing tumor samples from subjects in need of treatment for tumors;
determining whether the tumors fall within a tumor subclass; and
stratifying the subjects based on the results of the determining step prior to performing the treating step.
97. **(Withdrawn)** The method of claim 95, further comprising the steps of:
providing tumor samples from subjects in need of treatment for tumors;
detecting expression or activity of a gene encoding the polypeptide of SEQ ID NO:1 in the samples; and
stratifying the subjects based on the results of the detecting step prior to performing the treating step.
98. **(Withdrawn)** The method of claim 95, further comprising the steps of:
providing tumor samples from subjects in need of treatment for tumors;
detecting expression or activity of a gene encoding the polypeptide of SEQ ID NO:2 in the samples; and
stratifying the subjects based on the results of the detecting step prior to performing the treating step.
99. **(Withdrawn)** The method of claim 95, further comprising the steps of:
providing tumor samples from subjects in need of treatment for tumors;
detecting expression or activity of a gene encoding the polypeptide of SEQ ID NO:3 in the samples; and
stratifying the subjects based on the results of the detecting step prior to performing the treating step.

100. **(Withdrawn)** The method of claim 95, further comprising the steps of:
providing tumor samples from subjects in need of treatment for tumors;
detecting expression or activity of at least two genes, wherein each of the genes encodes a polypeptide whose sequence comprises a sequence selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, and SEQ ID NO:3 in the samples; and
stratifying the subjects based on the results of the detecting step prior to performing the treating step.

101. **(Withdrawn)** A method of testing a compound or a combination of compounds for activity against tumors comprising steps of:
treating subjects in need of treatment for tumors with the compound or combination of compounds or with an alternate compound, wherein the tumors fall within a tumor subclass;
comparing the response rate of tumors treated with the compound or combination of compounds with the response rate of tumors treated with the alternate compound; and
identifying the compound or combination of compounds as having superior activity against tumors in the tumor subclass, as compared with the alternate compound, if the response rate of tumors treated with the compound or combination of compounds is greater than the response rate of tumors treated with the alternate compound.

102. **(Withdrawn)** The method of claim 101, further comprising the steps of:
providing tumor samples from subjects in need of treatment for tumors;
determining whether the tumors fall within a tumor subclass; and
stratifying the subjects based on the results of the determining step prior to performing the treating step.

103. **(Withdrawn)** The method of claim 101, further comprising the steps of:
providing tumor samples from subjects in need of treatment for tumors;
detecting expression or activity of a gene encoding the polypeptide of SEQ ID NO:1 in

the samples; and

stratifying the subjects based on the results of the detecting step prior to performing the treating step.

104. **(Withdrawn)** The method of claim 101, further comprising the steps of:

providing tumor samples from subjects in need of treatment for tumors;

detecting expression or activity of a gene encoding the polypeptide of SEQ ID NO:2 in the samples; and

stratifying the subjects based on the results of the detecting step prior to performing the treating step.

105. **(Withdrawn)** The method of claim 101, further comprising the steps of:

providing tumor samples from subjects in need of treatment for tumors;

detecting expression or activity of a gene encoding the polypeptide of SEQ ID NO:3 in the samples; and

stratifying the subjects based on the results of the detecting step prior to performing the treating step.

106. **(Withdrawn)** The method of claim 101, further comprising the steps of:

providing tumor samples from subjects in need of treatment for tumors;

detecting expression or activity of at least two genes, wherein each of the genes encodes a polypeptide whose sequence comprises a sequence selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, and SEQ ID NO:3 in the samples; and

stratifying the subjects based on the results of the detecting step prior to performing the treating step.

107. **(Withdrawn)** The method of any of claims 101, 102, 103, 104, 105, or 106, wherein the alternate compound is a compound approved by the U.S. Food and Drug administration for treatment of tumors.

108. **(Withdrawn)** A method of treating a subject comprising steps of:
identifying a subject as having a tumor in a basal tumor subclass; and
administering a compound identified according to the method of any of claims 85, 86, 87,
or 90 to the subject.
109. **(Withdrawn)** A method of treating a subject comprising steps of:
identifying a subject as having a tumor in a basal tumor subclass; and
administering a compound identified according to the method of any of claims 95, 96, 97,
98, 99, or 100 to the subject.
110. **(Withdrawn)** A method of treating a subject comprising steps of:
identifying a subject as having a tumor in a basal tumor subclass; and
administering a compound identified according to the method of any of claims 101, 102,
103, 104, 105, or 106 to the subject.
111. **(Withdrawn)** A method of treating a subject comprising steps of:
providing a subject in need of treatment for cancer;
administering to the subject an antibody that specifically binds to a polypeptide having an
amino acid sequence comprising the sequence of SEQ ID NO:1.
112. **(Withdrawn)** A method of treating a subject comprising steps of:
providing a subject in need of treatment for a tumor;
administering to the subject an antibody that specifically binds to a polypeptide having an
amino acid sequence comprising the sequence of SEQ ID NO:2.
113. **(Withdrawn)** A method of treating a subject comprising steps of:
providing a subject in need of treatment for a tumor;
administering to the subject an antibody that specifically binds to a polypeptide having an

amino acid sequence comprising the sequence of SEQ ID NO:3.

114. **(Withdrawn)** The method of any of claims 111, 112, or 113, wherein the tumor is a breast tumor, and wherein the method further comprises the step of:

identifying the tumor as belonging to a basal tumor subclass.

115. **(Withdrawn)** The method of any of claims 111, 112, or 113, wherein the antibody is conjugated with a toxic molecule.

116. **(Withdrawn)** A method of treating a subject comprising steps of:

providing a subject in need of treatment for cancer;

administering to the subject a compound that activates or inhibits a gene that encodes an amino acid having a sequence comprising the sequence of SEQ ID NO:1, or that activates or inhibits an expression product of the gene.

117. **(Withdrawn)** A method of treating a subject comprising steps of:

providing a subject in need of treatment for a tumor;

administering to the subject a compound that activates or inhibits a gene that encodes an amino acid having a sequence comprising the sequence of SEQ ID NO:2, or that activates or inhibits an expression product of the gene.

118. **(Withdrawn)** A method of treating a subject comprising steps of:

providing a subject in need of treatment for a tumor;

administering to the subject a compound that activates or inhibits a gene that encodes an amino acid having a sequence comprising the sequence of SEQ ID NO:3, or that activates or inhibits an expression product of the gene.

119. **(Withdrawn)** A composition comprising:

two or more compounds identified according to the method of any of claims 85, 95, or

101.

120. **(Withdrawn)** A pharmaceutical composition comprising:
the composition of claim 119; and
a pharmaceutically acceptable carrier.

121. **(Withdrawn)** A composition comprising:
a compound identified according to the method of any of claims 85, 95, or 101;
a second compound, wherein the second compound is approved by the U.S. Food and
Drug administration for the treatment of cancer or has shown potential efficacy against cancer in
pre-clinical studies.

122. **(Withdrawn)** A pharmaceutical composition comprising:
the composition of claim 121, and a pharmaceutically acceptable carrier.